



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,826	09/16/2003	Bradford W. Gutting	84554	8902

23501 7590 04/17/2006

NAVAL SURFACE WARFARE CENTER, DAHLGREN DIVISION
OFFICE OF COUNSEL, CODE XDC1
17320 DAHLGREN ROAD
DAHLGREN, VA 22448-5110

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
----------	--------------

1651

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,826

Applicant(s)

GUTTING ET AL.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 10-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election with traverse of Group II, claims 2-9 on 2/10/06 is acknowledged. The traversal is on the ground(s) that at least Groups II and IV should be rejoined because both sets of claims involve germinants and are classified in the same class. However, this is not found persuasive because Group II is a method of producing one or more germinants and group IV is a process of using one or more germinants. With respect to group Group III, the claim 10 is directed to a product, the patentability of which does not depend on the process of making the product. Applicant has not provided evidence to demonstrate that the product disclosed by the cited reference, is, in fact, different from the product by process as claimed herein.

For purposes of the initial restriction requirement a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02. A different field of search exists where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries. Thus a different field of search is shown, even though the two are classified together broadly in the same large and diverse class.

An undue burden would ensue from the examination of multiple compositions or processes which have distinct characteristics and a process of use or different process steps and result in different product or effect. Burden lies not only in the search of U.S. patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant.

Clearly different searches and issues are involved with each group.

Art Unit: 1651

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 1 and 10-20 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague, indefinite and incomplete in lacking a proper process step such as culturing. There is no clear indication in the invention as claimed as to how provision of spores and macrophages "effective to produce germinant" results, in fact, in the production of a germinant in the absence of culture media and at refrigerator temperatures, for example.

In addition, claims 2-9 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claim 3 lacks proper antecedent basis for "the added spores".

Claim 4 is incomplete in lacking punctuation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1651

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ireland *et al.* taken with ATCC Catalogue and Citri.

The claims are directed broadly to a process of making a germinant by providing macrophages IC-21 and adding spores. In dependent claims the germinant is filtered.

Ireland *et al.* teach a process of making a germinant by providing macrophages and adding spores. The step of adding spores occurs at 10:1 macrophages to spores, for example. See, e.g., Figure 1. That a suitable germinant is produced is evidenced by germination efficiency (Table 3), particularly for spores of *B. anthracis*.

The reference differs from the invention as claimed in that the macrophages are not IC-21. However, the ATCC Catalogue adequately demonstrates that this particular cell line is old and well known in the art. In addition, Citri discloses that various germinants for spore-formers such as *Bacillus* strains are known in the art, such as inosine, glucose, L-alanine, L-proline, etc. See, e.g., Table 2.

One of ordinary skill in the art would reasonably have expected that substitution of a substantially similar cell lines similarly derived from macrophage result in the of a germinant for a spore producing microorganism such as *Bacillus*, particularly since suitable germinants are known to be available in culture media.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Ireland *et al.* of producing a germinant with a macrophage cell line and spores by replacing the macrophages of Ireland with IC-21 macrophages as suggested by the teachings of the ATCC Catalogue and Citri for the expected benefit of obtaining a suitable germinant for the effective and rapid detection of pathogenic or deleterious spore-producing microorganisms.


Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651